REMARKS

If any extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net addition of claims) are hereby authorized to be charged to our Deposit Account No. 11-0600.

Claims 28-112 are pending. Applicants submit that the amendments serve to correct obvious errors and do not constitute new matter. MPEP 2163.07. Accordingly, the amendments contained herein introduce no new matter.

If there the Examiner has any questions or concerns, he is invited to call the undersigned.

Respectfully submitted,

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Date 9/30/02

By _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Specification

Please replace the paragraph on page 4, lines 13-25, with the paragraph below

(Twice amended) Rather than administering the hydrogel lining via a coating on a balloon, the catheter may include a delivery port for administering a hydrogel to the inner surfaces of the stent. For example, the balloon may include a first layer and a second outer apertured layer overlaying the delivery port. The hydrogel is administered through the outer apertured layer of the balloon to contact the inner surfaces of the stent to create a lining therein. After the hydrogel is applied to the stent, a crosslinking agent may be administered to contact the hydrogel. For example, an [aginate] alginate hydrogel can be crosslinked by contacting it with calcium gluconate, and a hyaluronic acid hydrogel can be crosslinked by contacting it with divinyl glycol.

Please replace the paragraph on page 5, lines 7-17 (paragraph **[0012]** in the Published Patent Application), with the paragraph below:

The invention also features a method for lining a stent which includes the steps of providing a catheter assembly including a balloon at least a portion of which is coated with a hydrogel over which is mounted an expansible stent in a contracted condition, introducing the assembly into a body lumen, and [inflating-the] inflating the balloon to lodge the stent in the body lumen and to release the hydrogel from the coated portion of the balloon to the inner surfaces of the stent to create a lining. Preferably, the body lumen is a blood vessel, more preferably it is an artery, such as an artery occluded by an arteriosclerotic plaque.

Please replace the paragraph bridging page 9, line 21 to page 10, line 25

(paragraph **[0030]** in the Published Patent Application), with the paragraph below:

Other hydrogel polymers, such as collagen, albumin, [derivitized] derivatized albumin, gelatin, polyvinyl alcohol (PVA), cellulosics, alginates, acrylics, HEMA, polyethylene glycols, polyethylene oxides, polyacids, polyanhydrides, and polyacrylamides can be used to coat the balloon. Like the poly(acrylic acid) polymer coating, these hydrogel polymers are released from the balloon onto the inner surfaces of a stent by compression of the coated balloon against the stent. The hydrogel

polymers used are swellable but not dissolvable. As a result, a sheath over the hydrogel-coated balloon is not required to prevent loss of the hydrogel coating prior to release onto the inner surface of the stent. However, a sheath may be used in any of the embodiments discussed herein to facilitate placement of the catheter and/or deployment of the catheter or stent. For simultaneous stent deployment and lining, an expansible stent in a contracted form is placed over the hydrogel-coated balloon portion of the catheter prior to introduction of the catheter/stent assembly into the body. A drug such as an anti-thrombogenic agent may be applied to the coating or incorporated into the coating. For example, a solution of 10,000 units sodium heparin (Fisher Scientific, Pittsburgh, PA; USP Grade; 1000 units/ml which is then added to 650cc distilled water) may be applied to the hydrogel coating by dipping the coated catheter into the heparin solution for about 1 minute at room temperature.

Please replace the paragraph on page 11, lines 9-27 (paragraph **[0033]** in the Published Patent Application), with the paragraph below:

As shown in Fig.1, a stent 50 is placed over the balloon catheter 51 which is coated with a hydrogel coating 52 in the presence or absence of a drug. The balloon 51 and stent 50 are advanced until [they-reach] they reach the region of the occlusion 53 in the vessel 54. After the balloon 51 and the stent 50 have been positioned inside the vessel 54, the stent 50 is radially expanded and the hydrogel coating 52 released from the balloon 51 onto an inner surface of the stent 50 by the admission of pressure to the balloon 51. As a result, the stent is compressed against the vessel wall 54 with the result that occlusion 53 is compressed, and the vessel wall 54 surrounding it undergoes a radial expansion. The pressure from inflating the balloon also releases the hydrogel coating 52 onto the inner surface of the stent 50, thus lining it. The stent 50 is held in position in the expanded stateas shown in Fig. 2. The pressure is then released from the balloon and the catheter is withdrawn from the vessel, leaving the hydrogel as a lining of the deployed stent, as shown in Fig. 3.

Please replace the paragraph bridging page 11, line 28 to page 12, line 7 (paragraph **[0034]** in the Published Patent Application), with the paragraph below:

In the embodiments in which the hydrogel stent lining contains a drug, the hydrogel and drug may be selected such that an initial high dosage is delivered to adjacent tissue upon initial compression of the hydrogel followed by a slow, sustained time-release of drug remaining in the hydrogel lining. Preferred hydrogel-drug combinations are those that employ a binding of the drug, such as electrostatic binding, e.g., by using a poly(acrylic acid) hydrogel in combination with an ammonium cation and heparin or urokinase. [-] In this case, the coating continues to release drug after

expansion of the stent and removal the balloon catheter. The stent may be a balloon-expansible stent as described above or a self-expanding stent, e.g., of the type formed with superelastic materials such as Nitinol.

Please replace the paragraph on page 15, lines 14-25 (paragraph **[0042]** in the Published Patent Application), with the paragraph below:

Stents have been used to treat vascular aneurisms such as aortic or [intercranial] intracranial aneurisms. Such stents are typically impermeable, e.g., they may be recovered with woven dacron, to prevent plood from entering and pooling in the aneurism. A problem with using an impermeable stent to treat vascular aneurisms is that blood flow to both affected and healthy regions of a blood vessel [are] is blocked by the stent. In many cases, [intercranial] intracranial aneurisms occur at a point of bifurcation of healthy vessels. In such a case, it is desirable to block blood flow to or from healthy collateral vessels.

Please replace the paragraph bridging page 15, line 26 to page 16, line 24 (paragraph **[0043]** in the Published Patent Application), with the paragraph below:

An open mesh stent, e.g., a branched stent (Nitinol Development Corporation), is deployed to the area of an aneurism. Since an open mesh stent changes the pattern of blood flow in the vessel in which it is deployed, blood may no longer enter and pool in the aneurism, obviating the need for further treatment. However, if the stent alone is not an effective treatment, a second procedure to line the stent to render it impermeable can be performed. An advantage of the stent lining method described herein is that selected areas of the stent, e.g., an area near or adjacent to an aneurism, may be lined, leaving other areas, e.g., areas of healthy tissue, areas of bifurcation, or areas in which healthy collateral vessels enter or exit, unlined. For example, a hydrogel polymer which is insoluble in blood can be delivered to the inner surface of a stent at the site of an aneurism using a balloon catheter. The polymer, e.g., poly (acrylic acid), can be delivered as a coating on a balloon portion of a catheter and released to the inner surface of a stent near or adjacent to an affected portion of the vessel by expansion of the balloon. Alternatively, a dacron patch may be adhered to [a-polymer] a polymer coating and delivered to the aneurism site for release to the inner surface of the stent at the aneurism site. The dacron patch itself may be coated with a polymer to facilitate its attachment to the inner surface of the stent. Thus, an open mesh stent is rendered impermeable only in the area of the polymer lining or dacron patch but remains permeable in unlined areas. As a result, the flow of blood in the lined portions of the stent is directed down the length of the stent rather than through the interstices of the stent. In unlined regions of the stent, blood can flow through the interstices of the stent, e.g., to or from collateral vessels.